CLAIMS

1. An assembly for measuring the concentration of an analyte in a biological matrix, comprising:

an implantable optical-sensing element, said implantable optical-sensing element comprising: a body; a membrane mounted on said body, said membrane and body defining a cavity for receiving said analyte, said membrane being substantially permeable to said analyte and substantially impermeable to background species in said biological matrix; and a refractive element disposed in said cavity;

a source for providing light of a first intensity onto said refractive element in said cavity;

a detector for receiving light of a second intensity from said cavity; and

a signal-processing and computing element optically coupled to said detector for comparing said first and second intensities, and relating said intensities to analyte concentration.

2. The assembly of Claim 1, wherein said body has a proximal end and a distal end, and wherein said refractive element comprises a plurality of plates sequentially arranged transverse to the longitudinal axis of said body.

3. The assembly of Claim 1, wherein said refractive element comprises at least one of plates, particles, beads and powders.

4. The assembly of Claim 1, wherein said refractive element comprises at least one of a porous fiber, a porous rod, a convoluted ribbon, and a convoluted fiber.

5. The assembly of Claim 1, wherein the refractive element has a refractive index within ±9% of the refractive index of said analyte.

6. The assembly of Claim 5, wherein the refractive index of said refractive element is within ±5% of the refractive index of said analyte.

7. The assembly of Claim 1, wherein the refractive element has a refractive index between 1.26 and 1.50.

8. The assembly of Claim 7, wherein said refractive index is between 1.31 and 1.45.

9. The assembly of Claim 1, wherein said refractive element comprises a moldable plastic.

10. The assembly of Claim 9, wherein said moldable plastic is poly(undecafluorohexyl acrylate), poly(decamethylene carbonate), poly(ethylene succinate), poly(ethylene oxide), poly(trifluoroethylene), poly(hexafluoropropylene), poly(methyl methacrylate), poly(ethylene), poly(oxy(diethylsilylene)), or poly(vinyl fluoride).

11. The assembly of Claim 10, wherein said moldable plastic is poly(methyl methacrylate) or poly(ethylene).

12. The assembly of Claim 1, wherein said membrane comprises a bipolar membrane having a cation-exchange layer and an anion-exchange layer.

13. The assembly of Claim 12, wherein said cation-exchange layer and said anion-exchange layer are bonded together, said cation-exchange layer comprising a cross-linked polystyrene sulfonate and said anion-exchange layer comprising a cross-linked poly(vinyl benzyl trimethyl ammonium chloride).

14. The assembly of Claim 12, wherein said membrane further comprises a third membrane layer bonded to one of said cation and anion-exchange layers, or bonded to said body, said third membrane layer capable of excluding macrosolutes.

15. The assembly of Claim 14, wherein said third membrane layer is a regenerated cellulose or polyamide membrane.

16. The assembly of Claim 14, wherein said third membrane layer is laminated to said bipolar membrane.

17. The assembly of Claim 14, wherein each of said bipolar membrane and said third membrane layer is independently mounted on said body at an edge of said body.

18. The assembly of Claim 14, wherein said third membrane layer is formed on said bipolar membrane by a casting process.

19. The assembly of Claim 1, wherein said body includes a proximal end and a distal end, said distal end of said body comprising a light-absorbing material.

20. The assembly of Claim 1, wherein said body includes a proximal end and a distal end, said distal end of said body comprising a transparent material.

21. The assembly of Claim 1, wherein said body comprises a moldable plastic.

22. The assembly of Claim 21, wherein said body has a "U"-shaped or "V"-shaped cross section.

23. The assembly of Claim 1, wherein a ratio of the first intensity and the second intensity is convertable into an electronic signal.

24. The assembly of Claim 23, further comprising a readout device for said electronic signal.

25. The assembly of Claim 24, wherein said readout device comprises an analog, digital or audio readout.

26. The assembly of Claim 1, wherein said source comprises a transmitter for transmitting said light of a first intensity onto said refractive element.

27. The assembly of Claim 26, wherein said transmitted light is transmitted by a semiconductor light source.

28. The assembly of Claim 27, wherein said semiconductor light source is a light-emitting diode.

29. The assembly of Claim 1, wherein said transmitted light has a wavelength between 400 nm and 1300 nm.

30. The assembly of Claim 1, wherein said detector comprises a photodiode.

31. The assembly of Claim 2, wherein said plates are sequentially spaced by no more than 10 µm.

32. The assembly of Claim 26, wherein said transmitted light and said received light are transported through one or more optical fibers.

33. An implantable optical-sensing element suitable for measuring the concentration of an analyte in a biological matrix, said optical-sensing element comprising:

a body; a membrane mounted on said body such that said body and said membrane define a cavity for receiving said analyte, said membrane being substantially permeable to said analyte, and substantially impermeable to background species in said biological matrix; and a refractive element disposed in said cavity, said

refractive element having a refractive index different from a refractive index of said analyte.

34. The optical-sensing element of Claim 33, wherein said body comprises two parallel, elongated members, and said refractive element comprises a plurality of plates, each plate having two faces, said plates being sequentially arranged between said elongated members and oriented generally perpendicular to said elongated members.

35. The optical-sensing element of Claim 34, wherein said plates are integral with said elongated members in a unit-body construction.

36. The optical-sensing element of Claim 33, wherein said membrane comprises a first membrane, said optical-sensing element further comprising a second membrane mounted on said body remote from said first membrane.

37. The optical-sensing element of Claim 33, wherein said refractive element comprises at least one of plates, particles, beads and powders.

38. The optical-sensing element of Claim 33, wherein said refractive element comprises at least one of a porous fiber, a porous rod, a convoluted ribbon, and a convoluted fiber.

39. The optical-sensing element of Claim 33, wherein the refractive element has a refractive index within ±9% of the refractive index of said analyte.

40. The optical-sensing element of Claim 39, wherein the refractive index of said refractive element is within ±5% of the refractive index of said analyte.

41. The optical sensing-element of Claim 33, wherein the refractive element has a refractive index between 1.31 and 1.45.

42. The optical-sensing element of Claim 33, wherein said refractive element comprises a moldable plastic.

43. The optical-sensing element of Claim 42, wherein said moldable plastic is poly(undecafluorohexyl acrylate), poly(decamethylene carbonate), poly(ethylene succinate), poly(ethylene oxide), poly(trifluoroethylene), poly(hexafluoropropylene), poly(methyl methacrylate), poly(ethylene), poly(oxy(diethylsilylene)), or poly(vinyl fluoride).

44. The optical-sensing element of Claim 42, wherein said moldable plastic is poly(methyl methacrylate) or poly(ethylene).

45. The optical-sensing element of Claim 33, wherein said membrane comprises a bipolar membrane having a cation-exchange layer and an anion-exchange layer.

46. The optical-sensing element of Claim 45, wherein said cation-exchange layer and said anion-exchange layer are bonded together, said cation-

exchange layer comprising a cross-linked polystyrene sulfonate and said anion-exchange layer comprising a cross-linked poly(vinyl benzyl trimethyl ammonium chloride).

47. The optical-sensing element of Claim 46, wherein said membrane further comprises a third membrane layer bonded to one of said cation and anion-exchange layers, said third membrane layer capable of excluding macrosolutes.

48. The optical-sensing element of Claim 47, wherein said third membrane layer is a regenerated cellulose or polyamide membrane.

49. The optical-sensing element Claim 33, wherein said body includes a proximal end and a distal end, said distal end of said body comprising a light-absorbing material.

50. The optical-sensing element of Claim 33, wherein said body includes a proximal end and a distal end, said distal end of said body comprising a transparent material.

51. The optical-sensing element of Claim 33, wherein said body comprises a moldable plastic.

52. The optical-sensing element of Claim 51, wherein said body has a "U"-shaped or "V"-shaped cross section.

53. An assembly for measuring the concentration of an analyte in a biological matrix, comprising: an implantable optical-sensing element comprising a body; a first semi-permeable membrane mounted on said body, said first semi-permeable membrane being permeable to said analyte, and impermeable to background species in said biological matrix, said first membrane and said body aligned to define a first cavity; a first refractive element disposed in said first cavity; a second membrane mounted on said body remote from said first membrane, said second membrane and said body aligned to define a second cavity; and a second refractive element disposed in said second cavity;

a source for providing light into each of said first and second cavities toward said respective first and second refractive elements;

a detector for receiving light from each of said first and second cavities; and

a signal-processing and computing element optically coupled to said detector for relating said received light to a concentration of said analyte.

54. The assembly of Claim 53, wherein said analyte comprises a first analyte, said first semi-permeable membrane being permeable to said first analyte and impermeable to a second analyte, and wherein said second membrane is permeable to said second analyte.

55. The assembly of Claim 54, wherein said second membrane is impermeable to said first analyte.

56. The assembly of Claim 55, wherein said second membrane is impermeable to said analyte.

57. The assembly of Claim 53, wherein said source comprises a light transmitter for transmitting light into each of said first and second cavities

58. The assembly of Claim 57, wherein said transmitted light has a wavelength between 400 and 1300 nm.

59. The assembly of Claim 53, wherein said detector comprises first and second channels, said first channel receiving light reflected from said first refractive element, and said second channel receiving light reflected from said second refractive element.

60. The assembly of Claim 53, wherein said received light is convertible by signal-processing and computing element into an electronic signal.

61. The assembly of Claim 60, said assembly further comprising a readout device for display of said electronic signal.

62. The assembly of Claim 61, wherein said readout device comprises an analog, digital or audio readout.

63. The assembly of Claim 53, wherein said body has a "└┴┘"-shaped cross-section.

64. The assembly of Claim 53, wherein said body has a "├┤"-shaped cross-section.

65. An implantable optical-sensing element suitable for measuring the concentration of an analyte in a biological matrix, said optical-sensing element comprising: a body; a first semi-permeable membrane mounted on said body, said first semi-permeable membrane being permeable to said analyte, and impermeable to background species in said biological matrix, said first membrane and said body aligned to define a first cavity; a first refractive element disposed in said first cavity; a second membrane mounted on said body remote from said first membrane, said second membrane and said body aligned to define a second cavity isolated from said first cavity; and a second refractive element disposed in said second cavity.

66. The optical-sensing element of Claim 65, wherein said analyte comprises a first analyte, said first semi-permeable membrane being permeable to said first analyte and impermeable to a second analyte, and wherein said second membrane is permeable to said second analyte.

67. The optical-sensing element of Claim 66, wherein said second membrane is impermeable to said first analyte.

68. The optical-sensing element of Claim 65, wherein said second membrane is impermeable to said analyte.

69. The optical-sensing element of Claim 65, wherein said body has a "└┴┘"-shaped cross-section.

70. The optical-sensing element of Claim 65, wherein said body has a "├┤"-shaped cross-section.

71. A method for measuring the concentration of an analyte in a biological matrix, said method comprising:

implanting an optical-sensing element in said biological matrix, said optical-sensing element comprising a body, a semi-permeable membrane mounted to said body, said semi-permeable membrane being permeable to said analyte, but impermeable to background species in said matrix, said semi-permeable membrane and said body defining a cavity, and a refractive element disposed in said cavity;

introducing primary light from a light-emitting source into said body of said optical-sensing element, and directing said primary light toward said refractive element;

collecting secondary light reflected from said optical-sensing element and transmitting said secondary light to a light-detecting device;

measuring an intensity of said secondary light, and evaluating said analyte concentration in said biological matrix by comparing said measured intensity of said secondary light with an intensity of said primary light.

72. The method of Claim 71, wherein said evaluation is carried out by means of an evaluation algorithm and a calibration.

73. The method of Claim 71, wherein said analyte comprises glucose, and said primary light has a wavelength in a spectral region wherein glucose has a minimal effect on absorption of said primary light.

74. A method for measuring the concentration of an analyte in a biological matrix, said method comprising

implanting an optical-sensing element in said biological matrix, said optical-sensing element comprising a body, a first membrane mounted to said body, a second membrane mounted on said body remote from said first membrane, at least one of said membranes being permeable to said analyte, but impermeable to background species in said biological matrix, said first and second membranes and said body defining a cavity, and a refractive element disposed in said cavity;

transmitting primary light from a light-emitting source into said cavity toward said refractive element;

collecting secondary light reflected from refractive element, and transmitting said secondary light to a light-detecting device;

measuring an intensity of said secondary light with said light-detecting device;

deriving said analyte concentration in said biological matrix from said measured intensity of said secondary light by means of an evaluation algorithm and a calibration.

75. The method of Claim 74, wherein said analyte is glucose, and said primary light has a wavelength in a spectral region wherein glucose has a minimal effect on absorption of said primary light.

76. A method for measuring the concentration of an analyte in a biological matrix, said method comprising:

implanting an optical-sensing element in said biological matrix, said optical-sensing element comprising: a body, a first semi-permeable membrane mounted on said body, a second semi-permeable membrane mounted on said body remote from said first semi-permeable membrane, said first semi-permeable membrane being permeable to said analyte, but impermeable to background species in said biological matrix, said body and said first membrane defining a first cavity, a first refractive element disposed in said first cavity, said body and said second membrane defining a second cavity isolated from said first cavity, and a second refractive element disposed in said second cavity;

transmitting primary light from a light-emitting source to said body, and directing respective streams of said primary light into said first cavity toward said first refractive element, and into said second cavity toward said second refractive element;

collecting light from said body resulting from reflection at said first refractive element and transmitting said light to a first channel of a light-detecting device;

collecting light from said body resulting from reflection at said second refractive element and transmitting said light to a second channel of said light-detecting device;

measuring the intensity of light collected from each of said first and second channels;

computing the concentration of an analyte in said biological matrix by comparing the intensity of the transmitted light and the light collected from each of said first and second channels.

77. The method of Claim 76, wherein said analyte comprises a first analyte, said first semi-permeable membrane being permeable to said first analyte and impermeable to a second analyte in said biological matrix, said second membrane being permeable to said second analyte; and wherein said computing step computes the concentration of each of said first and second analytes.

78. An assembly for monitoring the concentration of an analyte in a biological matrix, comprising:

an implantable optical-sensing element, said implantable optical-sensing element comprising: a body; a membrane mounted on said body, said membrane and body defining a cavity for receiving said analyte, said membrane being substantially permeable to said analyte and substantially impermeable to background species in said biological matrix; and a refractive element disposed in said cavity;

a source for providing light of a first wavelength and a second wavelength into said cavity, said refractive element having a refractive index greater than the refractive index of the analyte at the first wavelength, and less than the refractive index of the analyte at the second wavelength;

a detector for receiving from said cavity an intensity of light at each of said first and second wavelengths at a first concentration of said analyte, and for receiving from said cavity an intensity of light at each of said first and second wavelengths at a second concentration of said analyte; and

a signal-processing and computing element optically coupled to said detector for comparing said intensities of light received at said first wavelength to said intensities of light received at said second wavelength, and relating said intensities to analyte concentration.

79. The assembly of Claim 78, wherein said source includes a beam splitter for splitting said light into light of at least two wavelengths.

80. The assembly of Claim 78, wherein said source comprises at least two light sources, each light source capable of providing light at a defined wavelength.

81. The assembly of Claim 78, wherein said detector comprises a detector member for detecting an intensity of light of said first wavelength, and a detector member for detecting light of said second wavelength.

82. A method for monitoring a change in the concentration of an analyte in a biological matrix of a test subject, comprising:

implanting an optical-sensing element in said subject, said implantable optical-sensing element comprising a body; a membrane mounted on said body, said membrane and body defining a cavity for receiving said analyte, said membrane being substantially permeable to said analyte and substantially impermeable to background species in said biological matrix; and a refractive element disposed in said cavity;

transmitting light of a first wavelength and a second wavelength into said cavity, said refractive element having a refractive index greater than the refractive index of the analyte at the first wavelength, and less than the refractive index of the analyte at the second wavelength;

collecting from said cavity an intensity of light at each of said first and second wavelengths at a first concentration of said analyte, and an intensity of light at each of said first and second wavelengths at a second concentration of said analyte; and

measuring said change in concentration of said analyte by comparing said intensities of light received at said first wavelength to said intensities of light received at said second wavelength for each of said first and second concentrations, and relating said intensities to changes in analyte concentration.